PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference		
P208356PCT	FOR FURTHER ACTION	See Form PCT/PEA/416
International application No. PCT/NL2004/000748	International filing date (day/month) 25.10,2004	Priority date (day/month/year) 24.10.2003
International Patent Classification (IPC) or na	Ilonal classification and IPC	
A23L1/29, A23L1/30, A61K31/733, A	61K31/702, A61K35/74, A61P	97.00
	•	·
Applicant		
N.V. NUTRICIA et al.		
1. This report is the international profit		
Authority under Article 35 and trans	minary examination report, estable initial to the applicant according	lished by this International Preliminary Exemining
2. This REPORT consists of a total of		
3. This report is also accompanied by		
a. 🖾 sent to the applicant and to	the International Bureau) a total c	of 3 sheets, as follows:
 aheets of the description and/or sheets containing Administrative instruction 		nave been amended and are the basis of this report Authority (see Rule 70.16 and Section 607 of the
 sheets which supersede beyond the disclosure in Supplemental Box. 	earlier sheels, but which this Au the international application as f	thorky considers contain an amendment that goes iled, as indicated in item 4 of Box No. I and the
b. Q (sent to the international But	THE PROPERTY OF STREET AND A STREET	and number of electronic carrier(s)) , containing a
	s related thereto, in computer rea sting (see Section 802 of the Adn	
Frankis to Godanies Fi	anny fara seption ans of me you	ministrative instructions).
4. This report contains indications relations	ing to the following items:	
Box No. I Basis of the opinion	ח	
☐ Box No. II Priorily		
☐ Box No. III Non-establishmen	t of opinion with regard to novelty	, inventive step and industrial applicability
HOX NO. IV Lack of unity of inv	rention	·
APPROXIMATION OF THE PROPERTY	nagar Article 35(2) with regard 2 gnihoqqua anoltanalqxe bna ana	i lo novelty, inventive step or industrial
Li Box No. VI Certain documents	cited	
Box No. VII Certain defects in	the international application	• •
☑ Box No. VIII Certain observation	ns on the international application	1
Date of submission of the demand		
cate of acolugation of the deligation	Date of comp	plation of this report
23.08.2005	15.12,200	5
Name and mailing address of the international preliminary examining authority:	Authorized O	Officer
European Palent Office		
D-80295 Munich Tel. +49 89 2399 • 0 Tx: 523656 6	Barnas, C	
Fax: +49 89 2399 - 4465	•	0. +49 89 2398-7469
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/NL2004/000748

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_	Box No. Basis of t	ne report .
1	With regard to the lang filed, unless otherwise	uage, this report is based on the international application in the language in which it was indicated under this item.
	minari in the lessing and	d on translations from the original language into the following language , ige of a translation furnished for the purposes of:
	☐ international sea ☐ publication of the	arch (under Rules 12.3 and 23.1(b)) e international application (under Rule 12.4) liminary examination (under Rules 55.2 and/or 55.3)
2.	. With regard to the elem have been furnished to	ents* of the international application, this report is based on (replacement sheets which the receiving Office in response to an invitation under Article 14 are referred to in this and are not annexed to this report):
	Description, Pages	
	1-34	es published
	Sequence listings part of	the description, Pages
	1-8	received on 03,01.2005 with letter of 03,01.2005
	Claims, Numbers	
	1-18	received on 23.08.2005 with latter of 22,08.2005
	Drawings, Sheets	•
	1, 2	benkalduq aa
	a sequence listing an	nd/or any related lable(s) - see Supplemental Box Relating to Sequence Listing
3.	☐ The amendments ha	ve resulted in the cancellation of:
	☐ the description, pa ☐ the claims, Nos.	iges
	the drawings, she	ets/jigs
	the sequence listing any table(s) relate	ng (spacity): d to sequence listing (spacify):
4. [☐ This report has been had not been made, since Supplemental Box (Rule 7	established as if (some of) the amendments annexed to this report and listed below they have been considered to go beyond the disclosure as filed, as indicated in the '0.2(c)).
	the description, pa	ges
	the drawings, shee	egigs
	the sequence listing any table(s) related	g (specify): 1 lo sequence listing (specify):
•		s, some or all of these sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/NL2004/000748

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

Claims

No:

1-18

Inventive step (IS)

Yes: Claims

1-18

No: Claims

Industrial applicability (IA)

Yes: Claims

1-18

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/NL2004/000748

1. V	Minus	
1. V	minde	ation of Box I, Item 2:
n	With n	egard to any nucleotide and/or amino acid sequence disclosed in the international application and sary to the claimed invention, this report has been established on the basis of:
а	ı. type	e of material:
	Ø	a sequence listing
	×	table(s) related to the sequence listing
b.	. form	nat of material:
	Ø	in written format
	Ø	in computer readable form
c.	. time	of filing/furnishing:
		contained in the international application as filed
		filed together with the international application in computer readable form
	Ø	furnished subsequently to this Authority for the purposes of search and/or examination
		received by this Authority as an amendment on
. 🖾	ado	addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating treating the second in the subsequent or distinguished, the required statements that the information in the subsequent or appropriate, were furnished.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

PCT/NL2004/000748

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The documents mentioned in the present International Preliminary Report are numbered as in the International Search Report. D1 corresponds to the first document of the Search Report, D2 to the second document etc.

Art. 33(3) PCT

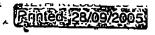
D2 discloses mixtures of at least two non-digestible soluble carbohydrate components having a different structure and differing in the average length by at least 5 monosaccharides. The problem to be solved is the provision of a carbohydrate mixture for improving the intestinal flora. The problem is solved by providing a preparation as described in claim 1 which, in addition, comprises Bifidobacterium breve. The cited prior and does not contain any hint that would prompt the skilled person to provide such a preparation. Claims 1-17 are therefore inventive. The cited prior art does also not contain any hint that would prompt the skilled person to use a mixture as described in claim 18 for the manufacture of a composition for decreasing the relative amounts of the indicated bacteria. Said claim is therefore also inventive.

Re Item VIII

Certain observations on the international application

Art. 6 PCT

The wording of claim 4 ("... wherein the carbohydrate components comprises 95 to 60 wt% and the carbohydrate B comprises 5 to 40 wt% with A+B=100%.") cannot be understood from the technical point of view. Said claim is therefore not clear, contrary to Art. 6 PCT. In view of the description of the present application said claim has been examined as "... wherein the carbohydrate component A comprises 95 to 60 wt% and the carbohydrate B comprises 5 to 40 wt% with A+B=100%."



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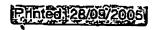
Amended claims



1. A preparation comprising Bifldobacterium breve and a mixture of at least two non-digestible soluble carbohydrate components A and B, wherein

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- said carbohydrate component A has a different structure from said carbohydrate component B;
 - said carbohydrate component A is present in an amount of 5 to 95 % by weight of the sum of carbohydrate components A and B;
 - at least 50% of the total non-digestible soluble carbohydrates is selected from disaccharides to eicosasaccharides; and
 - carbohydrate components A and B differ in the (average) number of monosaccharide units, carbohydrate component A having an average chain length which is at least 5 monosaccharide units lower than the average chain length of component B.
- 2. A preparation according to claim 1, wherein said carbohydrate components A and B differ in the structure of the monosaccharide units of the carbohydrate.
- 3. A preparation according to claim 1 or 2, wherein said carbohydrate component A is selected from indigestible monosaccharides up to hexasaccharides of the same carbohydrate structure, and said carbohydrate component B is selected from indigestible heptasaccharides and higher polysaccharides of the same carbohydrate structure.
- A preparation according to any one of claims 1-3, wherein the carbohydrate
 components comprises 95 to 60 wt% and the carbohydrate B comprises 5 to 40 wt%, with A + B = 100 wt%.
- A preparation according to any one of claims 1-4, wherein at least 60 wt%, preferably 80 to 100 wt% of said carbohydrate component A belong to the group of galacto-oligosaccharides, preferably to the group of trans-galacto-oligosaccharides.







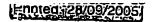
2

- 6. A preparation according to any one of claims 1-5, wherein at least 60 wt%, preferably 80 to 100 wt% of said carbohydrate component B belong to the group of fructo-polysaccharides, including inulin.
- 5 7. A preparation according to any one of claims 1-6, comprising 10⁵ to 10¹¹ cfu of Bifidobacterium breve per g of total non-digestible soluble carbohydrate.
 - 8. A preparation according to any one of claims 1-7 for use as a supplement, wherein the probiotic Bifldobacterium breve is present in the supplement in an amount of 1x10⁵ to 1.5x10¹¹ cfu/g, calculated on the basis of the supplement.
 - 9. A preparation according to any one of claims 1-7 for use as an infant nutrition, wherein the Bifidobacterium breve is present in the supplement in an amount of 1×10^2 to 1×10^{12} cfu/g of the infant supplement.

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- 10. An infant nutrition supplement comprising a preparation according to any one of claims 1-8, and further comprising digestible carbohydrate, a lipid source, or a protein source, or a mixture thereof.
- 20 11. An infant nutrition comprising a preparation according to any one of claims 1-7 and 9, and further comprising digestible carbohydrate, a lipid source, and a protein source.
- 12. Use of a preparation according to any one of claims 1-9 for the manufacture of a composition for the normalisation of the Bifidobacterium species composition in the gastro-intestinal tract of non- or partially breast-fed infants to the composition in breast-fed infants.
- 13. Use of a preparation according to any one of claims 1-9 for the manufacture of a
 30 composition for the prevention or treatment of one or more immune disorders.



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- 14. Use according to claim 13, wherein said immune disorders are selected from allergy, atopy, allergic rhinitis, food hypersensitivity, atopic dermatitis, eczema and asthma.
- 5 15. Use according to claim 13 or 14, wherein said immune disorders are selected from diarrhoea and viral diarrhoea.
 - 16. Use of a preparation according to any one of claims 1-9 for the manufacture of a composition for preventing and/or treating energy malabsorption.
 - 17. Use of a preparation according to any one of claims 1-9 for the manufacture of a composition for inhibiting the infiltration of eosinophils, neutrophils and mononuclear cells in allergic lesions, inhibiting the Th2 type immune response and/or stimulating the Th1 mediated immune response.
 - 18. Use of a mixture of at least two non-digestible soluble carbohydrate components A and B, wherein
 - said carbohydrate component A is present in an amount of from 5 to 95 % by weight of the sum of carbohydrate components A and B;
 - at least 50% of the total non-digestible soluble carbohydrates is selected from disaccharides to eicosasaccharides; and
 - said carbohydrate components A and B differ (i) in the (average) number of monosaccharide units of the carbohydrate, (ii) in the structure of the monosaccharide units of the carbohydrate, or (iii) both,
- 25 for the manufacture of a composition for decreasing the relative amounts of Bifidobacterium catenulatum, B. pseudocatenulatum and/or B. adolescentis in the gastro-intestinal tract of non- or partially breast-fed infants.





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